# DARWIN EU® – Paracetamol prescribing and paracetamol overdose in Europe: a descriptive analysis of trends and patient characteristics

**First published:** 22/05/2025

**Last updated:** 05/11/2025

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS1000000584

**Study ID**

1000000584

**DARWIN EU® study**

Yes

**Study countries**

- ☐ Denmark
- ☐ France
- ☐ Germany

- [ ] Netherlands
- [ ] Norway
- [ ] Spain
- [ ] Sweden

**Study description**

Paracetamol (acetaminophen) is one of the most widely used medicines worldwide and is available over the counter in the European Union.
It is one of the most common causes of drug poisonings and can result in severe hepatic failure.
Different regulatory interventions at national level have occurred to reduce the incidence of paracetamol overdose, but it is uncertain how paracetamol is prescribed across Europe and to what extent prescription may be involved in poisonings.

**Study status**

Ongoing

# Research institutions and networks

## Institutions

### Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

Netherlands

**First published:** 03/11/2022

**Last updated:** 02/05/2024

Institution | Educational Institution | ENCePP partner

## Networks

### Data Analysis and Real World Interrogation Network (DARWIN EU®)

- [ ] Belgium
- [ ] Croatia
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Portugal
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

**First published:** 01/02/2024

**Last updated:** 30/04/2025

Network

# Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Berta Raventos

Primary lead investigator

# Study timelines

**Date when funding contract was signed**

Planned: 24/03/2025

Actual: 24/03/2025

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**Study start date**

Planned: 05/05/2025

Actual: 05/05/2025

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**Date of final study report**

Planned: 30/09/2025

# Sources of funding

- EMA

# Study protocol

DARWIN EU_Protocol_P4-C2-002_Paracetamol OD_V2.pdf (772.08 KB)

# Regulatory

**Was the study required by a regulatory body?**

Yes

**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

# Methodological aspects

# Study type

# Study type list

**Study topic:**

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

**Study design:**

Retrospective cohort studies will be conducted using routinely collected health data from 8 databases.

**Main study objective:**

The aim of the study is to provide an overview of paracetamol prescribing and paracetamol overdose in the selected European databases, and to characterise patients presenting with paracetamol overdose.

The specific objectives of the study are:

1. To examine the incidence/prevalence of paracetamol prescribing (overall, and by age, sex, formulation and country/database).
2. To examine the incidence of paracetamol overdose (overall, and by age, sex, country/database).
3. To characterise patients with paracetamol overdose, in terms of comorbidities, co-prescribed medications, prior paracetamol prescription, and incidence of short-term complications and mortality.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name, other**

Paracetamol

## Population studied

**Short description of the study population**

The source population will comprise all individuals present in the database at any time during the period from 1st of January 2010 to 31st of December 2023 (or last year with complete observation). All patients will need to have at least 365 days of data visibility prior to index date. Therefore, children aged <1 year will be excluded.

## Documents

**Study report**

DARWIN EU_Report_P4-C2-002_Paracetamol OD_V3.0.pdf (2.82 MB)

# Data management

## ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

**Data source(s)**

Danish Health Data Registries

InGef Research Database

Integrated Primary Care Information (IPCI)

Norwegian Linked Health registry at University of Oslo

**Data source(s), other**

Hospital Universitario 12 de Octubre, Health Impact - Swedish Population Evidence Enabling Data-linkage

**Data sources (types)**

Electronic healthcare records (EHR)

# Use of a Common Data Model (CDM)

**CDM mapping**

Yes

**CDM Mappings**

**CDM name**

OMOP

**CDM website**

https://www.ohdsi.org/Data-standardization/

**CDM version**

https://ohdsi.github.io/CommonDataModel/index.html

# Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

Unknown